K081770
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510(k) Summary
Black Widow Anterior Buttress Plate

APR - 2 2009

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the Black Widow Anterior Buttress Plate

Date Prepared: June 18, 2008

1. **Submitter:**
Omni Surgical, LP
5000 Plaza on the Lake, Suite 305
Austin, Texas 78746

Contact Person:
Joshua Kaufman
Spine 360
5000 Plaza on the Lake, Suite 305
Austin, TX 78746
Telephone: 512-772-3774

2. **Trade name:** Black Widow Anterior Buttress Plate
Common Name: Buttress plate
Classification Name: Spinal intervertebral body fixation orthosis
Class II
21 CFR 888.3060
KWQ

3. **Predicate or legally marketed devices which are substantially equivalent:**
The Black Widow Anterior Buttress Plate is substantially equivalent to the MacroPore OS Spinal System (K010911).

4. **Description of the device:**
The Black Widow Anterior Buttress Plate is designed for preventing migration or expulsion of allograft or autograft in the thoracolumbar to S1 spinal region. Specific system features include:

- Plate uniquely shaped to conform to anterior spine anatomy.
- Two pegs which engage the vertebral body and prevent rotation.
- An extremely low profile plate with a full radius around the perimeter and a screw that sits flush with the anterior surface of the staple.
- A self-tapping screw in multiple lengths.

Materials:
The devices are manufactured from Ti6Al4V per ASTM F136.

Function:
The plates are designed to be used in spinal fusion procedures to provide stabilization and buttressing of tissue in the intervertebral space.

5. **Intended Use:**
The Black Widow Anterior Buttress Plate System, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing.

6. **Comparison of the technological characteristics of the device to predicate and legally marketed devices:**
The Black Widow Anterior Buttress Plate is similar in terms of design and intended use as the MacroPore OS Spinal System cleared via K010911.

7. **Summary of Nonclinical Tests**
Mechanical test results, conducted in accordance with ASTM F1717, demonstrate that the Black Widow Anterior Buttress Plate System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Omni Surgical, LP
% Mr. Joshua Kaufman
5000 Plaza on the Lake, Suite 305
Austin Texas, 78746

APR - 2 2009

Re: K081770
Trade/Device Name: Black Widow Anterior Buttress Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: February 13, 2009
Received: February 19, 2009

Dear Mr. Kaufman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K081770

Device Name: Black Widow Anterior Buttress Plate System

Indications for Use:

The Black Widow Anterior Buttress Plate System, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing applications.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081770